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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,799	04/13/2001	Enno Christophers	3774-4	1948
23117	7590	02/17/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			DUFFY, PATRICIA ANN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/833,799	CHRISTOPHERS ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-43 is/are allowed.
- 6) ☒ Claim(s) 26-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed October 9, 2003 and the supplementary amendment filed November 14, 2003 have been entered into the record. Claims 1-25 have been cancelled. Claims 26-43 are pending. Claims 26-43 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The objection to the Title is withdrawn based on Applicants amendment.

The rejection of Claims 8-13, 15-18, 24 and 25 under 35 U.S.C. 101 is withdrawn based on cancellation of the claims.

The rejection of claims 21 and 24 under 35 U.S.C. 112, first paragraph as new matter, is withdrawn in view of the cancellation of the claims.

The rejection of claims 8-13 and 15-18 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the cancellation of the claims.

The rejection of claims 8-13, 15-18 and 21-25 under 35 U.S.C. 112, second paragraph is withdrawn in view of the cancellation of the claims.

The rejection of claims 8, 11, and 15 under 35 U.S.C. 102(b) as anticipated by New England Biolabs Catalog 1986/87 is withdrawn in view of the cancellation of the claims.

The rejection of claims 12, 13, 17 and 18 under 35 U.S.C. 102(b) as anticipated by Maniatis et al, (Molecular Cloning A Laboratory Manual, Cold Spring Harbor laboratory, 1982) is withdrawn in view of the cancellation of the claims.

Rejections Maintained

Claims 26-36 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art at that the inventor(s), at the time that the application was

Art Unit: 1645

filed, had possession of the claimed invention for reasons made of record for claims 8-13, 15-18 and 21-25 in the Office action Mailed 4-9-03.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the revision of the claims to recite specific sequences obviates the rejection. This is not persuasive, the issue remains with respect that the claims read on full length genes and sequences comprising the described inhibitory fragment. The specification fails to disclose the full length cDNA sequence or encoding sequence and as such is not entitled to "comprising" language set forth in the claims. The same issue remains for "fragments" of the disclosed peptides. The claims are not limited to "portions", but any nucleic acid sequence comprising such. Applicants have not described such fragments or larger complete peptide sequence or the corresponding DNA sequences to show that Applicant was "in possession of the claimed invention" at the time the application for a patent was filed. Applicants have not described any fragments of the claimed sequence that have the alleged activity. Since the claimed genus of "comprising" nucleic acids encompasses undisclosed gene, partial genomic sequences and genes yet to be discovered, the disclosed structural feature does not constitute a substantial portion of the claimed genus. Applicants argue for the fragments that one could make and test to find portions that are operable and that the specification at pages 25 and 26 provides examples of polypeptides that include fragments of the "formula I" sequence that possess elastase inhibitory activity. It is respectfully submitted that make and test is not the standard for written description issues with regard to the claimed nucleic acids. Either, the specification describes inhibitory portions within a larger sequence and the complete gene sequence etc or it does not. Further, page 25 of the specification teaches that the major and minor inhibitory polypeptides were "partially sequenced" and therefore the components listed bridging pages 56-26 below are not inhibitory fragments or portions of Formula I that have inhibitory activity as asserted. There is no evidence that the partial sequences listed in the specification, as derived from a larger inhibitory sequence actually

Art Unit: 1645

possess inhibitory activity. In the instant case, the complete nucleotide sequence encoding the complete open reading frame for "Formula I" is not described and as such, Applicants do not have written description of the genus of comprising nucleic acids encoding inhibitory polypeptides as claimed.

The rejection is maintained.

The rejection of claims 26-35 under 35 U.S.C. 102(e) as anticipated by Remold-O'Donnell is maintained for reasons made of record for claims 7, 8, 9, 11, 12, 13, 15, 16, 17, 18 and 21-25.

The claims are still drawn to a fragment of the amino acid sequence that possess inhibitory activity against human leukocyte elastase. Applicants argue that the fragment must possess inhibitory activity. The claims do not recite this limitation. Given the claim construction reciting "said amino acid sequence that possesses inhibitory activity", it is the recite amino acid sequence and not the fragment per se that has inhibitory activity. Therefore, because the sequence of the prior art has inhibitory activity against human monocyte elastase (which by definition are leukocytes) and has a single amino acid in common with the claimed human elastase inhibitor, the nucleotide sequence of the prior art meets the limitation of the claims.

New Rejections Based on Amendment

Claims 34 and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by New England Biolabs Catalog 1986/87.

The claims are drawn to "a complement" of "a nucleotide sequence". Therefore, the claims read on complements that are shorter than the full length of the entire nucleotide sequence. As such, the Eco-RI linkers taught by New England Biolabs Catalog anticipate the claimed invention because they comprise nucleotides that have in common a single nucleotide and therefore represent "a complement" to at least one nucleotide of "a

Art Unit: 1645

nucleotide sequence" as claimed. Amendment of the claims to recite the full complement of the full length nucleotide sequence would obviate this issue.

Status of Claims

Claims 37-43 are allowed. Claims 26-36 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

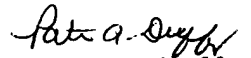
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Patricia A. Duffy
Primary Examiner
Art Unit 1645